

REMARKS

Applicants have received and reviewed the Office Action dated January 27, 2010. By way of response, Applicants submit the following remarks and the accompanying Declaration of Dr. Elisabetta Merlo. For the reasons presented below, Applicants respectfully submit that the present claims are in condition for allowance, and notification to that effect is earnestly solicited.

Rejection of Claims Under 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 4, 7 and 9-12 under 35 U.S.C. 103(a) as obvious over International Journal of Toxicology, 2001 in view of Methmanus-Spaltro, US 6,162,775. The Examiner rejected claims 1, 4 and 7-12 under 35 U.S.C. 103(a) over Gerber et al., US 5,653,988 in view of International Journal of Toxicology. The Examiner rejected claims 1, 4 and 7-12 under 35 U.S.C. 103(a) over International Journal of Toxicology in view of Stork et al., US 6,620,773. Applicants respectfully traverse these rejections.

International Journal of Toxicology in view of Methmanus-Spaltro

The present independent claim recites a "composition is in the form of a liquid" that includes "between 10% and 40% by weight" a compound that can be an acyl sarcosinate. In contrast, the cited International Journal of Toxicology (IJT) reference discloses liquid soaps including only 2.78% and 6.86% sodium lauroyl sarcosinate (page 5, left column). This reference discloses bar (i.e., solid) soaps including 12.5% and 19.9% sodium lauroyl sarcosinate (page 5, left column). As noted by the examiner, the reference also discloses 2.78% to 12.9% sodium lauroyl sarcosinate in soaps (page 12, right column). Taking the reference as a whole, the IJT reference teaches that liquid soaps include less only low concentrations of sodium lauroyl sarcosinate of 2.78% and 6.86%, which is well below the range recited in the present claim for liquid compositions. Therefore, the IJT reference neither teaches nor suggests the presently claimed invention.

The secondary Methmanus-Spaltro reference does not remedy the shortcomings of the IJT reference. This secondary reference discloses employing water soluble glycerine and polyethylene glycol (PEG) and certain "water insoluble benefit agents". The water insoluble benefit agents are used at concentrations of up to 20% (abstract), more preferably 0.1-10%

(column 6, lines 36-38). In contrast, in addition to the surfactant discussed above, the presently claimed composition includes "one or more oily substances at a total concentration within the range of between 30% and 70% by weight relative to the composition". Thus, the secondary reference discloses only amounts significantly below the "between 30% and 70% by weight" recited for oily substances in the present claim 1. Therefore, this secondary reference does not remedy the shortcomings of the primary IJT reference.

The Office Action dwells on the disclosure by the Methmanus-Spaltro reference of employing water soluble glycerine and polyethylene glycol (PEG) in cosmetic compositions. The oily substances recited in the present claim 1 are not glycerine or PEG and are not as water soluble as glycerine and PEG. The disclosure of water soluble glycerine and PEG does not teach or suggest the oily substances recited in the claim. Again, the combined IJT and Methmanus-Spaltro references neither teach nor suggest the presently claimed invention.

Applicants respectfully submit that it is well known that an oil is a substance which is liquid at ambient temperature, which is hydrophobic, and which has a large oil/water partition coefficient. In contrast, water soluble substances (e.g., glycerine and PEG) are hydrophilic and are characterized by low oil/water partition coefficients. Page 4347 of the Merck Index, 10th Edition (submitted herewith as Exhibit A) shows that glycerol (which is also called glycerin or glycerine) is fully miscible with water. Furthermore, the octanol/water partition coefficient of glycerol ($\log K_{o/w}$) is -1.76, indicating that glycerol is a hydrophilic substance. Further, the $\log K_{o/w}$ of acetamide, i.e. a hydrophilic substance, is -1.16 and that the $\log K_{o/w}$ of 2,2',4,4',5-pentachlorobiphenyl, a lipophilic substance, is 6.41. The above data clearly show that glycerol is a hydrophilic substance and that it is not an oily substance.

The same applies to PEGs, which are known to be water soluble and hydrophilic substances. For example, the partition coefficient of PEG 400 between hexane and water is $\log P = -4.8$.

Such data concerning the water solubility and the partition coefficients of glycerol and PEGs are very basic common general knowledge and are readily available, for example, from the Internet. See for example <http://www.inchem.org/documents/icsc/icsc/eics0624.htm> for the \log of glycerol; http://en.wikipedia.org/wiki/Partition_coefficient for the $\log K_{o/w}$ of acetamide and 2,2',4,4',5-pentachlorobiphenyl; http://en.wikipedia.org/wiki/PEG_400 for the $\log P$ of PEG 400.

Thus, these properties of glycerol and PEGs, which we believe are well within the basic scientific knowledge of any graduate in chemistry.

Accordingly, based on the foregoing differences, Applicants submit that the cited references neither teach nor suggest the presently claimed compositions, and withdrawal of this rejection is earnestly solicited.

Gerber et al. in view of International Journal of Toxicology and International Journal of Toxicology in view of Stork et al.

To address these rejections, Applicants respectfully submit herewith the Declaration of Dr. Elisabetta Merlo (Exhibit B) and three Annex's to this Declaration (Exhibits C, D, and E). Exhibits C and D are each a report of experimental data. Exhibit E is Dr. Merlo's curriculum vitae. Exhibits A, C, D, and E accompany this response. Applicants' undersigned representative will forward the Declaration (Exhibit B) when the signed copy is received.

Exhibit C (Annex 1) presents an experimental study of the eye irritation potential of a sample designated as "Sample A", which is a market leader bath oil, and a sample designated as "Sample B", which is a bath oil containing oleoyl sarcosine, which is an N-acylate of amino acid according to claim 1. In addition, sodium lauryl sulphate (SLS) was included in the experimental set as an irritant positive control.

The market leader bath oil (Sample A of Exhibit C) is a mixture of conventional surfactants consisting of cocamide DEA, laureth-4 and MIPA-laureth sulphate in bath oil. Such a surfactant mixture is commercially available as ZETESOL 100.

The experimental report of Exhibit C further contains the results obtained with a third formulation, designated as "Sample C". Such results, as well as any information relating thereto, have been deleted because Sample C does has nothing to do with the present patent application.

Exhibit D (Annex 2) presents a second experimental report on the eye irritation potential of a cosmetic product, designated as "Sample A", which is oleoyl sarcosine in water. sodium lauryl sulphate (SLS) was again selected as the irritant positive control.

The detailed compositions of the cosmetic formulations tested in Exhibits C and D are provided in the Dr. Merlo's Declaration (Exhibit B).

The results obtained from the irritation tests are expressed in terms of inhibiting

concentration 50 (IC₅₀), which is the concentration of the test formulation which is capable of inducing a 50% decrease in the cell growth/survival. The IC₅₀ value is commonly used as an indication of the potential irritating effect of a test compound or formulation, and consequently of its tolerability. Of course, the lower the IC₅₀, the lower the tolerability.

Applicants respectfully submit below a Table summarizing the experimental results reported in Exhibits C and D:

SAMPLE	IC ₅₀
Exhibit C:	
SLS	0.029
Sample A (market leader bath oil)	0.072
Sample B (oleoyl sarcosine bath oil)*	0.72
Exhibit D:	
SLS	0.0427
Sample A (oleoyl sarcosine in water)	0.03
* according to the invention	

These results demonstrate that a formulation according to the present invention (Sample B, Exhibit C) has a measure of tolerability that is one order of magnitude higher than a composition including conventional surfactants (Sample A, Exhibit C).

The composition according to the present invention includes oleoyl sarcosine and is much more tolerable than the conventional formulation. However, oleoyl sarcosine in water is not well tolerated. This is shown by the results presented in Exhibit D. Oleoyl sarcosine is tolerated only as well as sodium laurel sulfate, another conventional surfactant.

It is the claimed combination of oily substances and surfactant that achieves the high tolerability. The cited references neither disclose nor suggest such high tolerability or that irritation by surfactants such as oleoyl sarcosine could be overcome.

Therefore, Applicants respectfully submit that the disclosure by the Gerber et al. reference or the Stork et al. reference of certain oily substances and together with the IJT reference would not have motivated one of skill in the art to arrive at the presently claimed invention.

Accordingly, based on the foregoing differences, Applicants submit that the cited references neither teach nor suggest the presently claimed compositions, and withdrawal of these rejections is earnestly solicited.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

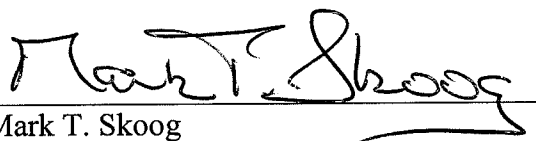
Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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